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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,377	03/10/2004	Qinglin Ma	2003P04030US01	4475

7590 09/22/2006

Siemens Corporation
Intellectual Property Department
170 Wood Avenue South
Iselin, NJ 08830

EXAMINER

LAURITZEN, AMANDA L

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,377

Applicant(s)

MA ET AL.

Examiner

Amanda L. Lauritzen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/10/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/10/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed provisional application 60/456,160 filed March 20, 2003 is acknowledged under 35 U.S.C. 119(e).

Information Disclosure Statement

2. Citing of reference(s) in the specification is not proper information disclosure. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, U.S. Patents cited in the specification are required to be officially documented in the information disclosure statement (form PTO-1449 or equivalent) to guaranty consideration by the examiner. U.S. Patent 5,490,512 is cited in the specification but does not appear on form PTO-1449. Please note that if this reference is not cited by the examiner on form PTO-892, it has not been considered.

Specification

3. The title of the invention is not descriptive of the inventive concept. A new title is required that is clearly indicative of the new matter to which the claims are directed.

The following title is suggested: SYSTEM, TRANSDUCER ARRAY AND METHOD FOR BOTH VOLUME FLOW RATE AND MEDICAL ULTRASOUND IMAGING.

4. The abstract of the disclosure is objected to because it is in excess of 150 words. Section MPEP § 608.01(b) states that the abstract of the disclosure is to be within the range of 50 and 150 words and is not to exceed 15 lines of text. Correction is required.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a).
6. Figure 10 is objected to because it fails to show numbering of the rows as referenced in the specification on pages 15 and 16. It is recommended that the origin of the rows and the last row in the sequence be indicated. As described in MPEP § 608.02(d), any detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing.
7. Furthermore, the drawings must show every feature of the invention specified in the claims. Therefore, the rows identified in claim 18 and depending claims 19 and 20 must be shown or the item(s) canceled from the claim(s). Additionally it is recommended that the kerf features of the transducer array in claims 17-20 be shown in an alternate perspective view, depicting the three dimensional structure, as it is not clear in the top view drawings of the transducer array submitted. No new matter should be entered.
8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet”

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

9. Claim 1 is objected to because step (a) is not fully understood as it is not known what the statement “measuring... as a function of acoustic energy transmitted” particularly encompasses. This statement does not advance the information provided in the preamble of “measuring... with ultrasound”. Appropriate correction is advised.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not understood what is meant by the phrase “with uniform sensitivity of the vessel”. Perhaps instead applicant means to claim either uniform sensitivity of the *imager* or uniform *insonification* of the vessel. For examination purposes it is construed as uniform sensitivity of the imager to provide uniform insonification of a vessel, particular to the attenuation compensated volume flow (ACVF) method of Hottinger and Meindl as cited in the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 9-12, 14, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fu et al. (U.S. Patent No. 4,431,936).

11. Regarding claims 1, 2, 9 and 11, Fu '936 discloses a method for measuring a volume flow parameter as a function of acoustic energy transmitted from an annular configuration of a plurality of transducer array elements and indicates use of the same array to acquire ultrasonic images. Fu further discloses transmitting a uniform far field acoustic pattern and receiving a wide and a narrow far field acoustic pattern (see col. 5, lines 53-64 where the beams are both generated and received). The volume flow parameter is calculated as a function of a first power associated with a uniform far field acoustic pattern and a second power associated with the narrow far field acoustic pattern (col. 3, lines 9-13). Though the processor used to make these calculations is not explicitly disclosed, such computation is known to require a processor to those skilled in the art. Likewise, a display is inherent in the viewing the images that are generated by the invention of Fu.

12. Regarding claims 3 and 12, though the disclosure of Fu '936 is not particular to specify 1.5D operation of the array to perform two-dimensional ultrasound imaging and measure of the flow parameter, it is well known to those skilled in the art to use 1.5D arrays for such purposes.

13. Regarding claim 5, Fu '936 details use of the ACVF method of Hottinger that is cited in applicant's specification to provide uniform insonification of the vessel (see col. 2, lines 54-59), according to how the examiner construes this claim as outlined in section 10 above.

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14. Regarding claims 6, 14 and 15, both imaging and volume flow measures are performed with the array of Fig. 10b of Fu '936 that shows an aperture of similar azimuth and elevation dimensions with at least three rows of elements, including a first group of elements formed into a ring annular element and a second group of elements arranged as a central annular element within the ring annular element, with both groups of annular elements being used in the measure of a volume flow parameter. Additionally, Fu discloses the use of at least one of the at least three rows of elements for imaging (see col. 7, lines 5-14; also Fig 10b, annular element 56 surrounding center annular element, and the row of imaging elements 58; see also central disc element referenced in claims 4 and 5 of Fu '936). The two-dimensional image is inherently responsive to at least one of the rows of elements, as some response is necessary for the image generation that Fu discloses as being accomplished with this array.

15. Regarding claim 10, array interconnections are inherent for communication between elements for any ultrasound application, but the examiner takes note that Fu '936 also cites array element interconnections in an alternate embodiment (see electrical connections in col. 6, lines 43-44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al. '936 in view of Nudell et al. (U.S. Patent No. 5,085,220). The Fu reference teaches all the features of the invention substantially as claimed, including the method of flow calculation based upon the power associated with two beams, but is not particular to disclose a first velocity measure in the calculation of the volume flow parameter. However, in the same field of endeavor, Nudell discloses the method for calculation of a volume flow parameter (i.e. cardiac output) that also includes transmission of two Doppler paths to obtain a first velocity and power associated with the first (i.e. wide beam) Doppler path and a second power associated with the second (i.e. narrow beam) Doppler path (col. 2, lines 37-44).

It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to have incorporated the volume flow parameter method of calculation as taught by Nudell '220 with the imaging system and volume flow measure method of Fu '936 in order to provide improved accuracy in measure of a volume flow parameter.

17. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al. '936 in view of Robinson et al. (U.S. Patent No. 6,419,633). Fu '936 discloses the invention substantially as claimed but is not particular to disclose image generation by of one of a B-mode

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or a Doppler mode. However, in the same field of endeavor, Robinson '633 cites both B-mode and Doppler mode two-dimensional imaging (col. 9, lines 28-29). These means of two-dimensional image generation as taught by Robinson were known at the time of the applicant's invention and would have been obvious to use in the system of Fu in order to provide the physician with the image view that is best suited for patient diagnosis.

18. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al. '936 in view of Ma (U.S. Patent No. 6,599,245). Fu '936 teaches all the features of the invention substantially as claimed, including providing different transmit waveform polarity (see field direction parameter in col. 4, lines 63-64), but is not specific to providing different apodization to different groups of elements simultaneously or focusing as a function of apodization delay. However, in the same field of endeavor, Ma '245 discloses a transmit apodization system that is capable of providing different apodization for each transducer element as they are determined separately according to the apodization function (col. 1, lines 41-43).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the apodization function of Ma '245 with the imaging and volume flow measuring system of Fu '936 in order to provide control of the acoustic power delivered for different groups of array elements for improved image quality (see col. 1, lines 21-25 of Ma '245).

19. Claims 8 and 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al. '936 in view of Stephens (U.S. Application Publication No. 2004/0054287) and Robinson et al. '633.

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The Fu '936 reference discloses all the features of the invention substantially as claimed, including a kerf structure separating the rows of transducer elements (see insulation between the transducer elements cited in claim 2 of Fu '936), but is silent regarding the detail of the kerf structure extending along the azimuth dimension a distance less than that of the first row of elements. However, in the same field of endeavor, Stephens '287 discloses that kerf structures isolate array elements from one another and further points out that cuts may extend the length of the row to fully isolate each row of elements or be left connected to each other by making cuts through only the middle portions of the row (para. 0097, lines 6-9). Hence, the kerf structures of Stephens are disclosed to extend along the azimuth dimension less than the first row or azimuth length and it therefore would have been obvious to one of ordinary skill in the art at the time of applicant's invention to have incorporated this feature with the system of Fu '936 for the purpose of acoustic decoupling of selected adjacent array elements (see Stephens '287 abstract, lines 10-13).

20. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al. '936 in view of Stephens '287 and Robinson et al. '633.

The invention of Fu '936 as modified by Stephens '287 teaches all the features of the instant invention but does not account for the multiplicity of rows in applicant's claims 19 and 20. However, Robinson '633 teaches a 19-row (azimuth direction), 19-column (elevation direction) "sparse" array in which there are inactive spaces between the active transducer elements (col. 3, lines 10-12). Further detailed are switches and coax cables that establish a connection to activate elements (col. 4, lines 48-50); therefore, any configuration of rows and/or elements can be established with this array, as long as it is within the 19-row, 19-column

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dimensions, so additional elements that extend from each azimuth side can be configured to have an elevation width that is substantially equal to the elevation width of the first row, second row, and kerf together, as in applicant's claim 19, or the width of the additional elements could be configured as greater than the width of the elements of each of the first through fifth rows, as in claim 20. As it has been shown, the structural configurations of transducer arrays cited in claims 19 and 20 are possible with the sparse transducer array of Robinson '633, and therefore these configurations and others accommodated by the sparse transducer array would have been known to those of ordinary skill in the art at the time of the applicant's invention and therefore obvious to be used in the transducer array associated with the invention of Fu '936 as modified by Stephens '287 for the purpose of providing improved image quality by increasing the number of array elements and/or rows.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Suorsa et al. (U.S. Patent No. 6,120,454) for an Annular array ultrasound catheter notes that annular transducer elements comprised of piezoelectric or piezoceramic materials require a nonconductive spacer or kerf to prevent acoustic signal transfer between elements (col. 5, line 65 – col. 6, line 4); Buck et al. (U.S. Patent No. 6,544,181) for a Method and apparatus for measuring volume flow and area for a dynamic orifice; Briskin (U.S. Patent No. 4,530,363) for a Transducer array for sector scan and Doppler flow measurement applications; Meindl (U.S. Patent No. 3,888,238) for Ultrasonic blood vessel imaging system and method.

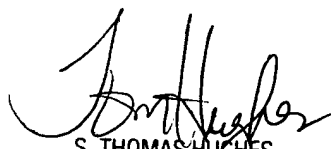
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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